

510(k) Summary – S8 ADVANCE System

Date Prepared 3rd October, 2008

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Classification Reference 21 CFR 868.5905

Product Code 73.BZD

Common/Usual Name Non continuous ventilator (IPPB):

Proprietary Name S8 ADVANCE

Predicate Device(s) S8 Escape II (K080079)
S8 Pioneer (K041209)

Reason for submission New Device

JAN - 2 2009

Indication for Use

The S8 ADVANCE self-adjusting sleep apnea system is indicated for the treatment of Obstructive Sleep Apnea (OSA) in adult patients.

The S8 ADVANCE system has two treatment modes: auto-titrating APAP and fixed-pressure CPAP.

The S8 ADVANCE system is intended for home and hospital use.

Device Description

The S8 ADVANCE System is similar to the predicate devices, (S8 Escape II and S8 Pioneer) with a micro-processor controlled blower system that generates Continuous Positive Airway Pressure (CPAP) from 4-20 cmH₂O as required to maintain an "air splint" for effective treatment of OSA. The system comprises the flow generator, patient tubing, mask (patient interface) and humidifier.

The performance and functional characteristics of the S8 ADVANCE system includes all the clinician and user friendly features of the S8 Escape II (K080079) with the addition of the auto-titrating mode equivalent to the S8 Pioneer (K041209).

Substantial Equivalence

The new device has the following similarities to the previously cleared predicate devices.

- Similar intended use
- Similar operating principle
- Similar technologies
- Same manufacturing process

Design and Verification activities were performed on the S8 ADVANCE System as a result of the risk analysis and product requirements. All tests confirmed the product met the predetermined acceptance criteria. ResMed has determined that the new device is Substantially Equivalent to the predicate devices. The new device complies with the applicable requirements referenced in the FDA guidance documents:

- FDA Draft Reviewer Guidance for Ventilators (July 1995)
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- FDA Off-the-Shelf Software Use in Medical Devices (September 9, 1999)

Conclusion

The S8 ADVANCE System is substantially equivalent to the S8 Escape II (K080079) and the S8 Pioneer (K041209).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 2 2009

ResMed Limited
C/O Mr. David D'Cruz
Vice President, Clinical & Regulatory Affairs
ResMed Corporation
14040 Danielson Street
Poway, California 92064-6857

Re: K082979
Trade/Device Name: S8 Advance
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: October 3, 2008
Received: October 6, 2008

Dear David D'Cruz:

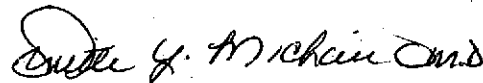
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: S8 ADVANCE

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Prescription Use ☒

AND/OR

Over-The-Counter Use ☐

(Part 21 CFR 801 Subpart D)

(Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

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(Division Sign-Off)Division of Anesthesiology, General Hospital
Infection Control, Dental Devices510(k) Number: K082979